

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION

MDL No. 2187

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THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES

MEMORANDUM OPINION AND ORDER  
(*Daubert* Motion re: Anthony B. Brennan, Ph.D.)

Pending in *In re C. R. Bard, Inc. 2:10-md-2187*, MDL 2187, is C. R. Bard, Inc. (“Bard”)’s *Daubert* motion<sup>1</sup> to Exclude or Limit Certain Opinions and Testimony of Anthony B. Brennan, Ph.D. [ECF No. 4565]. The motion is now ripe for consideration because the briefing is complete. As set forth below, Bard’s motion is **GRANTED in part and DENIED in part**.

**I. Background**

These groups of cases reside in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation (“MDL”) concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 29,000 cases currently pending, approximately 3,000 of which are in the C. R. Bard, Inc. MDL, MDL No. 2187.

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<sup>1</sup> Rather than refile, Bard entered a “notice” adopting prior *Daubert* motions that incorporate the parties positions previously formulated in Waves 1 and 2.

In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a “wave” of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order (“PTO”) # 236, *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:10-md-02187, Jan. 27, 2017, <https://www.wvsc.uscourts.gov/MDL/2187/orders.html>. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general experts in the main MDL, MDL 2187, and to identify which cases the motion would affect.

## **II. Legal Standard**

Under Federal Rule of Evidence 702, expert testimony is admissible if it will “help the trier of fact to understand the evidence or to determine a fact in issue” and (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods” which (3) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to “prove” anything. However, he or she must “come forward with

evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: “[E]xpert witnesses have the potential to be both powerful and quite misleading”; the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I “need not determine that the proffered expert testimony is irrefutable or certainly correct” – “[a]s with all other admissible evidence, expert testimony is subject to testing by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Md. Cas. Co.*, 137 F.3d at 783 (“All *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful.”).

*Daubert* mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the

relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We agree with the Solicitor General that ‘[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.’” (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* also explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of “fit.” “Fit” is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702’s “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

*Daubert*, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

### III. Analysis

Bard seeks to exclude certain opinions of Anthony B. Brennan, Ph.D. Dr. Brennan is a biomedical engineer who has “evaluated and continue[s] to evaluate numerous explants to determine behavior in the human body.” Notice by Pls. of

Adoption of Prior Daubert Resp. to Mot. to Exclude or Limit Certain Ops. & Test. of Anthony Brennan, Ph.D. (“Pls.’ Mem. re: Brennan”) Ex. 1 at 2 [ECF No. 4593-1].

Bard moves to exclude Dr. Brennan’s opinions and conclusions concerning: (1) polypropylene or mesh, their degradation, or their material characteristics; (2) SEM, EDS, FTIR, HPLC data and results and any opinions related to or relying upon those results or reports; (3) GPC, DSC, and TGA data and results and any opinions related to or relying upon those results or reports; (4) data, testing, or examination performed on explants “cleaned” of tissue by Dr. Brennan, Dr. Garth Wilkes, or Polymer Solutions; (5) effects the Bard mesh products have on the human body or medical injuries or conditions they may cause, including inflammation; (6) pore size of the Bard mesh products or Bard’s measurement thereof; (7) Dr. Brennan’s pore size measurements of the Bard mesh products; (8) MSDS of any kind, including of raw material of the Bard mesh products; and (9) biocompatibility of the Bard mesh products and testing or standards thereof. *See* Notice of Adoption of Mot. to Exclude or Limit Certain Ops. & Test. of Anthony Brennan Ph.D in Wave 4 & Wave 5 Cases (“Bard’s Mem. re: Brennan”) Ex. C at 2–3 [ECF No. 4565-3]. Broadly, Bard offers five arguments in support of excluding Dr. Brennan’s opinions. I proceed to address each in turn.

1. Effect of Mesh on the Body—Inflammation & Degradation<sup>2</sup>

First, Bard argues that Dr. Brennan is not “competent” to testify regarding the effects of Bard’s mesh products on the plaintiffs or the human body because he lacks

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<sup>2</sup> Bard’s first two arguments with regard to inflammation and degradation can be disposed of together.

the proper medical education or background. *Id.* at 4. Dr. Brennan’s expert report notes that he is “knowledgeable about a number of chemical fields including polymeric biomaterials, polymeric materials . . . physical and chemical aging of polymers and nanocomposites and the design, manufacturing, testing, clinical evaluation and distribution of medical devices for both short-term and long-term implantation.” Pls.’ Mem. re: Brennan at 2. Clearly, as a biomedical engineer, Dr. Brennan has extensive education and experience in biomaterials generally—which includes polymers—as well as knowledge of how these materials respond when implanted in the human body. Accordingly, I **FIND** that Dr. Brennan is qualified to offer opinions on the effect of polypropylene mesh on the human body.

Bard also contends that Dr. Brennan’s inflammation opinions are unreliable because he did not review any medical records, pathology slides, or histology slides of the individual plaintiffs. *See* Bard’s Mem. re: Brennan at 6. The plaintiffs concede that Dr. Brennan is not offering any specific causation opinions in this case. Dr. Brennan’s failure to examine individual records or slides, therefore, does not affect the reliability of his opinions generally.<sup>3</sup> In discussing inflammation and degradation, Dr. Brennan cites multiple peer-reviewed articles and refers to his own testing of explant samples. Accordingly, I **FIND** Dr. Brennan’s general opinions on the effect of polypropylene mesh on the human body sufficiently reliable under *Daubert*. I **DENY** Bard’s motion on this point.

## 2. Polymer Solutions Testing

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<sup>3</sup> As I previously stated, issues regarding specific causation are moot given the parties decision to adopt and incorporate a *Daubert* motion addressing other multidistrict litigation plaintiffs.

Next, Bard argues that Dr. Brennan's opinions based on testing performed by Polymer Solutions should be excluded because he lacked the qualifications to perform the testing himself and the cleaning methodology was inadequate. *Id.* at 10. Bard's first argument with regard to the testing performed by Polymer Solutions is misplaced. Dr. Brennan collaborated with Dr. Wilkes and Polymer Solutions—an accredited laboratory—to conduct the testing at issue. *See* Pls.' Mem. re: Brennan at 9. Dr. Brennan provided written protocols for the testing, and both doctors were often present to direct and oversee what took place in the laboratory. *Id.* at 9–10. The fact that a third-party laboratory physically performed the testing is not sufficient to prohibit Dr. Brennan from relying on such testing. In fact, the plaintiffs point out that Bard's expert, Dr. Reitman, engaged in a similar practice. Furthermore, in his deposition, Dr. Brennan explicitly stated that he has conducted similar testing on his own before. Pls.' Mem. re: Brennan at 9 ("I've done extensive FTIR testing on my own for years."). Accordingly, I **FIND** that Dr. Brennan properly relied on the testing performed by Polymer Solutions.

Bard also contends that the cleaning methodology employed by Polymer Solutions was inadequate, invalidating the testing entirely. Dr. Brennan, Dr. Wilkes, and Polymer Solutions developed a cleaning protocol based on literature, experience, and other scientific information. *Id.* at 14. In his deposition, Dr. Brennan explained that some remaining tissue would not affect his ability to observe degradation and that such an occurrence is to be expected. *See id.* at 15–16 ("I can clearly see the degradation on the sample. So the tissue isn't an issue at this point."). Based on

Dr. Brennan's testimony, I am satisfied that the cleaning methodology was sufficiently reliable under *Daubert*. Accordingly, I **FIND** that Dr. Brennan's opinions based on the testing performed by Polymer Solutions should not be excluded, and I **DENY** Bard's motion on this issue.

### 3. Pore Size

Next, Bard argues that Dr. Brennan is unqualified to perform pore size testing and that his methodology is not representative of conditions in the human body. *See* Bard's Mem. re: Brennan at 15. I reviewed Dr. Brennan's qualifications and the reliability of his pore size opinions under *Daubert* previously. *See Bard*, 948 F. Supp. 2d at 638–39. The parties in this case assert the same arguments; therefore, my reasoning and conclusions from *In re C.R. Bard, Inc.* govern. In *Bard*, I ruled as follows:

After review of Dr. Brennan's report and deposition testimony, and the parties' arguments, I **FIND** that to the extent Dr. Brennan relies on his tensile testing to render opinions related to how mesh performs inside the female pelvis, such opinions should be excluded; these opinions would not assist the jury because the tensile testing is not intended to represent how mesh performs inside the female pelvis. However, opinions derived from tensile testing regarding the effect of stress on the mesh are admissible. I further **FIND** that Dr. Brennan is qualified to testify as to pore size, and that his opinions are based on reliable principles and methodology and properly applies to the facts of the case.

948 F. Supp. 2d 589, 639 (S.D. W. Va. 2013). Accordingly, I **ADOPT** my prior ruling on Dr. Brennan, as stated in *Bard* and **FIND** that he is qualified to opine on pore size and that his opinions are reliable, with the exception of his opinions related to how



mesh performs inside the female pelvis based on tensile testing. Thus, I **DENY in part** and **GRANT in part** Bard's motion to exclude this opinion.

#### 4. MSDS and Biocompatibility

Last, Bard contends that Dr. Brennan's MSDS and biocompatibility opinions are "unreliable and contradictory." Bard's Mem. re: Brennan at 18. It is unclear to me how this argument is any different from Bard's arguments with regard to Dr. Brennan's other opinions on polypropylene. I have already determined that Dr. Brennan is qualified to opine on polypropylene generally, as well as polypropylene degradation, and that his opinions are reliable. I see no reason to depart from those findings merely because Bard opposes Dr. Brennan's references to the MSDS and biocompatibility. Furthermore, "[l]istening to testimony and deciding whether it is contradictory is the quintessential jury function of determining credibility of witnesses." *Crowley v. Chait*, 322 F. Supp. 2d 530, 553–54 (D.N.J. 2004) (internal quotation marks omitted). Accordingly, I **FIND** that Dr. Brennan is permitted to offer opinions that include references to the MSDS and biocompatibility testing.

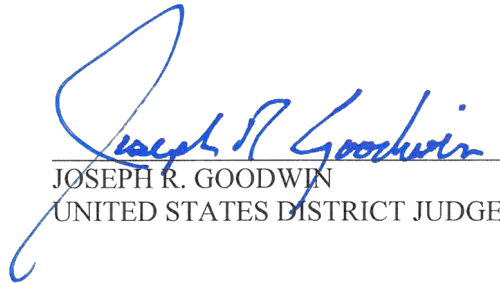
#### IV. Conclusion

To summarize, I **GRANT in part** and **DENY in part** Bard's motion concerning Anthony B. Brennan, Ph.D. [ECF No. 4565] consistent with my reasoning above.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the

Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: January 23, 2018



JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE

# **EXHIBIT A**

PLAINTIFF	CURRENT CIVIL ACTION #	WAVE
Barker, Lorie	2:13-cv-33690	4
Bivens, Geraldine L	2:16-cv-11116	4
Black, Brenda L	2:14-cv-00952	4
Branscome, Christine E	2:16-cv-10995	4
Brewer, Pamela R	2:16-cv-11135	4
Brown, Cathy	2:16-cv-10807	4
Carnahan, Kathy	2:13-cv-24208	4
Cooley, Dedra	2:14-cv-07543	4
Cuffee, Carolyn D	2:14-cv-02528	4
Degarmo, Nora	2:12-cv-07578	4
Drake, Theresa	2:16-cv-03709	4
Edwards, Claudine	2:14-cv-27463	4
Ford, Janet Marie	2:14-cv-09878	4
Gardiner, Gloria	2:13-cv-15209	4
Gilbert, April D	2:16-cv-11118	4
Gritten, Linda	2:16-cv-03707	4
Guerrero, Angelia	2:14-cv-14209	4
Hall, Cardisa M	2:16-cv-11113	4
Henderson, Teresa	2:16-cv-03779	4
Holmes, Robin	2:13-cv-01524	4
Hummel, Niki	2:13-cv-32359	4
Johnson, Nancy	2:13-cv-19736	4
Jones, Thelma J	2:16-cv-03719	4
Keisling, Linda	2:16-cv-03721	4
Lackey, Danielle R	2:16-cv-11011	4
Landers, Samantha	2:13-cv-26574	4
Ledwein, Judy	2:16-cv-03778	4
Lee, Frankie	2:12-cv-07570	4
Long, Pamela D	2:13-cv-20881	4
Martin, Judy A	2:16-cv-11103	4
Massey, Shannon L.	2:14-cv-01027	4
McWilliams, Brenda K	2:16-cv-11104	4
Miller, Alice F	2:16-cv-11014	4
Moore, Carol	2:16-cv-03842	4
Moore, Carolyn S	2:14-cv-00606	4
Morgan, Khristina S	2:16-cv-11016	4
Nadeau, Susan J	2:16-cv-11112	4
Nall, Stephanie	2:13-cv-01526	4
Newell, Carmen	2:13-cv-16405	4
Phelps, Inna V	2:16-cv-11114	4
Pickering, Hope	2:16-cv-03896	4
Politi-Topal, Kathleen D.	2:14-cv-01411	4
Powell, Mary C	2:16-cv-11017	4

PLAINTIFF	CURRENT CIVIL ACTION #	WAVE
Powers, Lisa R	2:16-cv-11041	4
Priddy, Judy M	2:13-cv-10318	4
Purcell, Kim	2:13-cv-34058	4
Radatz, Mary L.	2:13-cv-17989	4
Raines, Cynthia Ann	2:13-cv-26748	4
Richardson, Cynthia O	2:13-cv-20036	4
Richardson, Demetria	2:12-cv-02564	4
Rodericks, Rhonda K	2:16-cv-11115	4
Rogers, Rosemary J	2:16-cv-11106	4
Sheaffer, Julie A	2:14-cv-05601	4
Silvia, Diane	2:14-cv-25366	4
Smith, Tamela	2:13-cv-30640	4
Speetzen, Michelle	2:13-cv-12416	4
Stapel, Catherine	2:14-cv-25362	4
Stewart, Mary Sue	2:14-cv-27466	4
Stoddard, Sloane	2:14-cv-11940	4
Struble, Maureen	2:16-cv-03817	4
Swiney, Ernestine F	2:16-cv-11021	4
Teeples, Mistie D	2:16-cv-11020	4
Toulson, Patricia	2:16-cv-03816	4
Urdike, Melody A	2:16-cv-11035	4
Weber, Erika	2:16-cv-11105	4
Wilson, Elizabeth J	2:14-cv-14119	4
Woodard, Elizabeth E	2:16-cv-11040	4
Alvey, Christine	2:16-cv-07705	5
Bailey, Carla	2:16-cv-06362	5
Barton, Joan	2:16-cv-07655	5
Bess, Joyce	2:16-cv-06318	5
Clarke, Janice	2:16-cv-10809	5
Cole, Jeanene	2:16-cv-07402	5
Collins, Dana	2:16-cv-06739	5
Corley-Davis, Celia	2:16-cv-10811	5
Crook, Julie	2:16-cv-06360	5
Crowe, Karen F	2:16-cv-11136	5
Currie, Arlene	2:16-cv-10814	5
Daily, Catherine T	2:16-cv-11137	5
Davis, Debra M	2:16-cv-11139	5
Dennis, Barbet	2:16-cv-10815	5
Donley, Teresa	2:16-cv-07322	5
Donovan, Thoris L	2:16-cv-11142	5
<del>Duncan, Andrea</del>	<del>2:16-cv-10816</del>	5
Ellis, Karen	2:16-cv-07694	5
Elrod, Josephine	2:16-cv-04032	5

PLAINTIFF	CURRENT CIVIL ACTION #	WAVE
Fay, Paula A	2:16-cv-11144	5
Frederick, Cheryl D	2:16-cv-11266	5
Hale-Cuellar, Patricia A	2:16-cv-11150	5
Hauber, Elizabeth A	2:16-cv-11158	5
Herrera, Wynde Lynn	2:16-cv-10819	5
Hill, Mignon M	2:16-cv-11161	5
Jasso, Mary	2:16-cv-06361	5
Jeffries, Lynda	2:16-cv-11798	5
Johnson, Elisa J	2:16-cv-11147	5
Josey, Tammy	2:16-cv-11803	5
Knernschiold, Peggy	2:16-cv-06743	5
Kolodzyk, Virginia L	2:16-cv-11163	5
Krishnan, Meera	2:16-cv-06740	5
Kyes, Marilyn	2:16-cv-11804	5
Leyba, Lorraine	2:13-cv-16401	5
Lingenfelter, Nancy	2:16-cv-07610	5
Mahnke, Joyce C	2:16-cv-11167	5
Martinez, Tammy	2:16-cv-10821	5
Mathis, Nellie	2:16-cv-08014	5
Miecznikowski, Jennifer C	2:16-cv-11169	5
Morrill, June	2:16-cv-11170	5
Nichols, Brandey R	2:16-cv-11186	5
Piper, Connie	2:16-cv-11811	5
Prince, Marjorie	2:16-cv-04949	5
Reynolds, Cassandra	2:16-cv-11175	5
Roberts, Carla	2:16-cv-06741	5
Roberts, Sheila	2:16-cv-05003	5
Smith, Sandra	2:16-cv-11817	5
Stephenson, Erin	2:16-cv-11819	5
Stevens, Terri L	2:16-cv-11820	5
Tatum, Tuesday	2:16-cv-11821	5
Thompson, Reba	2:16-cv-04536	5
Watson, Charlotte	2:16-cv-03989	5
Yoder-Brady, Bobbye	2:16-cv-03954	5
Young, Carolyn	2:16-cv-04037	5